K120372

Always More Marketing Inc
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JUN 27 2012

510(k) SUMMARY

Summary Prepared on 2-3-2012

Contact Person:
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Name of Device: Dr Greenburgs Hybrid Vacuum

Common or Usual Name: Anti-Snoring and Apnea Device

Classification Name: Anti-Snoring Device (21CFR872.5570)

Product Code: LRK

Predicate Devices:
Dr Greenburgs Hybrid (K111680)
SomnoGuard (K061688)
Respire Blue Series (K111207)
Full Breath (K091035)
Silent Nite (K972424)
EMA (K971794)

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Description of the Device:

The Dr Greenburgs Hybrid Vacuum Anti-Snoring Device is a removable intraoral device for repositioning the upper and lower jaw into a prescribed relationship for a single patient to use multiple times at home or sleep laboratories.

The Dr Greenburgs Hybrid Vacuum Device is a two piece, upper and lower arch tray system that includes an additional elastic component which impedes the tongue from falling back into the airway. The tray system is designed to posture the lower jaw into several elective positions, with the intent to increase the airway passage opening, while the additional elastic component aids in keeping the airway open by impeding the tongue from falling back and blocking the airway.

The combined effect of the advancement of the lower jaw, and the elastic impeding the tongue from falling back into the airway reduces snoring and breathing arrests due to obstructive sleep apnea.

Dr Greenburgs Hybrid Vacuum has a front area opening that is large enough for emergency breathing.

Dr Greenburgs Hybrid Vacuum Snoring appliance consists of two independent trays (Top and Bottom), and an elastic that is connected between the trays located posteriorly. The trays consist of The trays consist of FDA approved, copolyester that gives strength and structural support. The elastic consists of a non-allergenic, latex free silicone. The elastic stretches from molar to molar across the tongue. It applies slight pressure to impede the tongue from falling back into the airway. The flexibility of the elastic allows movement of the tongue, aiding in swallowing and comfort. The frictionless silicone helps to prevent any tongue irritation. The retaining elastic is held firmly onto the bottom tray via securing buttons and is locked securely between the two trays.

The top and bottom trays alignment are determined by the length connecting bands that are attached via buttons on the sides of the top and bottom trays. This system moves the jaw forward to achieve the most therapeutic position.

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Indications for Use: Dr Greenburgs Hybrid Vacuum Anti-Snoring Device is indicated for persons 18 years or older, who wish to reduce the incidence of snoring and/or mild to moderate obstructive sleep apnea.

Technological Characteristics: Dr Greenburgs Hybrid Vacuum device has the following similarities to the previously cleared predicate devices:
Same intended use.
Same operating principle.
Same technology.
Same manufacturing process.

All of the predicates and Dr Greenburgs Hybrid Vacuum act as mandibular repositioners for the treatment of snoring and mild to moderate Obstructive Sleep Apnea.

Dr Greenburgs Hybrid Vacuum, the Full Breath (K091035), and Dr Greenburgs Hybrid (K111680) all have tongue retaining components.

Dr Greenburgs Hybrid Vacuum, the Silent Nite (K972424) EMA (K971794) and Dr Greenburgs Hybrid (K111680) use straps/bands held onto button attachments.

Substantial Equivalence is based on non-clinical data.

In addition the literature supports the historical significance of oral devices that reposition the jaw and reduce and manage snoring as well as sleep apnea.

The Abstract Oral Appliances for Snoring and Obstructive Sleep Apnea: A Review from SLEEP, Vol. 29, No. 2, 2006 Page 259 states… "Overall, those with mild to severe OSA have a 52% chance of being able to control their sleep apnea using an appliance. OAs are on the whole less effective than CPAP but may be better accepted by patients than nasal CPAP in studies where subjects used both treatments." Also, "They are well tolerated by most patients" and "Published literature now provides evidence for the efficacy of OAs in the treatment of patients with mild to moderate OSA"

Based on clinical data, it is demonstrated in a variety of articles that looked at oral appliances and their use for the treatment of snoring and sleep apnea, oral appliance therapy is an effective means by which these conditions can be managed. This effectiveness is embraced from a variety of aspects including safety, convenience and cost.

Clinical data provided (Jonathan Greenburg's Sleep Study Table) illustrates patients can improve their sleep apnea disease significantly if they use an intraoral anti-snoring device with a tongue retaining component during sleep.

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A risk assessment concluded that there were no new safety concerns raised by the design of Dr Greenburgs Hybrid Vacuum.

In conclusion, a number of studies have shown improvement of the airway during sleep utilizing imaging associated with the use of oral appliances (also referred to as Oral Airway Dilators), aid in the management and reduction of snoring and sleep apnea. In addition the clinical data that was provided (Jonathan Greenburg's Sleep Study Table) illustrates patients can improve their sleep apnea disease significantly if they use an intraoral anti-snoring device with a tongue retaining component during sleep.

In summary, the device described in this submission is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 27 2012

Jonathan Greenburg, DDS
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Re: K120372
Trade/Device Name: Dr Greenburgs Hybrid Vacuum
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices for Snoring and Intraoral Devices for Snoring and Obstructive Sleep Apnea.
Regulatory Class: II
Product Code: LRK
Dated: May 29, 2012
Received: June 5, 2012

Dear Dr. Greenburg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K120372

Indications for Use

510(k) Number (if known):

Device Name: Dr Greenburgs Hybrid Vacuum

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who wish to reduce the incidence of snoring and/or mild to moderate

obstructive sleep apnea

Prescription Use ☑ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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